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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,719	03/21/2002	Armin Johannes Becker	13390.2USWO	8053
23552	7590	02/27/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			SAOUD, CHRISTINE J	
			ART UNIT	PAPER NUMBER
			1647	
DATE MAILED: 02/27/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/018,719	BECKER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christine J. Saoud	1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 12-18 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 12-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>032102</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I in Paper filed 15 October 2003 is acknowledged. The traversal is on the ground(s) that the variety of active ingredient would not require extensive further examination. This is not found persuasive because the restriction was based on a lack of unity for the inventions claimed; i.e. different special technical features for each invention. Lack of unity is based on the lack of a common special technical feature, not on the extent of further examination or search burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed October 15, 2003.

### ***Claim Objections***

Claim 12 is objected to because of the following informalities: "female" is spelled incorrectly (e.g. "femaled"). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 12 recites a "method of treating female and male sexual functional disorders comprising an effective amount of a growth hormone". However, the specification does not teach how to treat both female and male sexual functional disorders at the same time by administration of a growth hormone to a single patient. The patient is either male or female, therefore, the claim should be directed to treatment of female OR male sexual functional disorders.

Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of an effective amount of growth hormone, does not reasonably provide enablement for administration of an effective amount of a growth hormone. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification discloses that growth hormone (GH or human growth hormone, hGH) is useful for the treatment of sexual functional disorders. However, the claims are not limited to GH or hGH, but rather recite administration of "a growth hormone". There is no correlation demonstrated in the instant specification between

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growth hormones in general (which include any hormone which stimulates growth) and treatment of sexual functional disorders. It is not predictive that other growth factors and hormones would function in the same manner as GH/hGH for the treatment of sexual functional disorders because other hormones that effect growth are not known to be implicated in sexual functional disorders. Therefore, it would require undue experimentation to determine which growth hormone other than GH/hGH is involved in sexual function and then determine an effective amount for the treatment of sexual functional disorders, which is not the standard for an enabling disclosure. If the claims were limited to the administration of "growth hormone" , rather than "a growth hormone", this ground of rejection could be avoided.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by SPENCER et al. (WO 98/42361).

Spencer et al. teach the treatment of a sexual functional disorder by the administration of GH. Spencer et al. additionally teach the administration of GH in combination with IGF or another growth factor (see page 5, 1<sup>st</sup> paragraph). Spencer et al. does not specifically mention administration to a growth hormone deficient patient,

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but claims administration for a disorder as the result of aging. The art is clear that growth hormone deficiency is a concomitant of aging, and therefore, this limitation is inherently met. Therefore, the claims are anticipated by the prior art.

**Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD  
PRIMARY EXAMINER

*Christine J. Saoud*